

REMARKS

Claims 68-83 are pending. No amendments have been made by way of the present submission, thus no new matter has been added.

In the outstanding Office Action the Examiner has alleged that the present application contains groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Thus, the Examiner has required that Applicants elect one of the following three groups:

Group I, claims 68-72, 74-76, 79-80, drawn to a plurality of species Helicobacter binding substances,

Group II, claims 73, 77, 82-83, drawn to a plurality of methods of treating or carrying out bindings assays with Helicobactor binding substances,

Group III, claim 78, drawn to oligosaccharide binding substance of a structurally different formula (A or B).

Applicants respectfully traverse. Applicants respectfully submit that the above three groups relate to a single general inventive concept under PCT Rule 13.1. Further, these claims share the same or corresponding special technical feature which represents a contribution over the prior art. The Examiner has alleged that this contribution is allegedly anticipated by the prior art.

In particular, the Examiner alleges that Ångström et al. (1998) anticipates a number of the present claims. Applicants disagree.

Ångström et al. describes *H. pylori* binding to certain lactosyl Gal $\beta$ 4Glc $\beta$ Cer comprising glycosphingolipids, which requires specific lipid (i.e. ceramide) structures for binding. The structures are not included in the structures of the present invention. More specifically, Ångström et al. discloses the binding of *H. pylori* to Gal $\beta$ 4Glc $\beta$ Cer sequence linked to a certain ceramide

structure (see compounds 5-7 in table 1, page 299). However, when the lactosylceramide does not comprise hydroxyl fatty acid on the ceramide, the glycosphingolipid structure does not bind to *H. pylori* (see compound 4 in Table 1, page 299). Moreover, it is shown by molecular modeling that a hydrogen bond between the 6-hydroxyl group of the glucose in Gal $\beta$ 4Glc $\beta$ Cer and the 2-hydroxyl group of the fatty acid in the ceramide is essential for the binding disclosed in the Ångström et al. (see Fig. 6 on page 303 and “Conformational Aspects” on page 303-304). Thus, Ångström et al. teaches that the *H. pylori* binding epitope is a large and complex conformational structure between Glc ring of the oligosaccharide part and a hydroxyl fatty acid hydrogen of the ceramide part bonded to Glc (Fig. 6 on page 303). Ångström et al. does not teach that Gal $\beta$ 4Glc $\beta$ Cer sequence alone or as part of any structures but the specific ceramide with hydroxyl fatty acid would be a *H. pylori* binding epitope.

The Examiner alleges that the present invention includes structures of Ångström et al, especially isoglobotriasyl ceramide and asialo-GM1. However, Ångström et al., does not describe active oligosaccharides but describes lactose based glycosphingolipid binding structures with the obligatory hydroxyl fatty acid structure. Therefore, the present invention does not include the glycolipid molecules of Ångström et al.

It should also be noted that the structures in Ångström et al. with the closest resemblance to the structures of the present invention did not bind *H. pylori* at al. (e.g. GlcNAc $\beta$ 3LacCer, structure number 13 of Table 1 of Angstrom et al.) or that the isoglobotriasyl-Cer is bound by *H. pylori* in the ceramide-dependent manner (e.g. Gala3LacCer structures number 11 and 12 of Ångström et al.). It is further noted that the formulas in the present claim 68 do not include structures with Gal $\beta$ 4Glc-epitope, when either r2 or q2 is 1.

The present invention also does not include asialoGM1-structures comprising Ga1 $\beta$ 3GalNAc $\beta$ 4Gal $\beta$ Cer disclosed by Ångström et al. The asialoGM1-structure is even more different from the structures of the present invention with characteristics of a GalNAc $\beta$ Gal-epitope with  $\beta$ 4 linkage to axial 4-hydroxyl of the Gal residue.

For the above reasons, Applicants submit that the outstanding allegations of lack of Unity of Invention are improper and should be withdrawn.

However, in order to be responsive to the outstanding Unity of Invention rejection, Applicants hereby elect Group II, directed to claims 73, 77, and 82-83. Further, concerning an election of species, Applicants hereby elect the species of treating one of the species Group I, for instance GalNAc $\beta$ 4Glc (A), more specifically Ga1NAcB4G1cA (i.e. s=0, r2=1, q2=1 and r3=0 in the Formula of claim 68).

It is Applicants understanding that this election of species serves as a starting point for search and examination purposes only. Upon indication of allowable subject matter the Examiner is required to expand the search to include other non-elected species, with the intent of finding the generic claims ultimately allowable.

In view of the above, favorable action on the merits is respectfully solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolas and Birch, LLP, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

- Attached is a Petition for Extension of Time.
- Attached hereto is the fee transmittal listing the required fees.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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